

Lab Result Interface (LRI) example IG

Subtitle this should map to HL7? If so, then need to add the unique name (supplied by HL7)

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# Introduction

The*HL7 Version 2.5.1 Implementation Guide:S&I Framework Lab Results Interface, Release 1 DSTU Release 2 " US Realm*is the result of collaborative efforts between HL7 and the Office of the National Coordinator (ONC) Standards andInteroperability (S&I) Framework Laboratory Results Interface (LRI) Initiative.By consensus the HL7 V2.5.1 ORU^R01 Message was selected as the basis to definethe profile constraints expressed in this guide to meet the requirements of thetransmission of laboratory results. The Standards and Interoperability(S&I) Frameworks Laboratory Result Interface Use Case was leveraged andrevised, where agreed upon by the working group, to provide the Use Casecontent, diagrams and foundation for this Implementation Guide. Capabilitiesmade available through HL7 V2.8.2 were selectively applied to further supportthe use case requirements.

## Purpose

The Laboratory ResultsInterface Initiative identifies the requirements, defines specifications andstandards to provide implementation guidance for electronic reporting oflaboratory test results to ambulatory care providers in the US Realm. The scopeof the Laboratory Results Interface Use Case includes requirements to enablethe incorporation of clinical laboratory test results into an Electronic HealthRecord System (EHR-S) as standardized structured data using the definedinter-organizational laboratory transaction. The Use Case requirements aredirected at laboratory test results reporting between a Laboratory InformationSystem (LIS) and an ambulatory EHR-S in different organizational entities,e.g., different corporate structure, ownership or governance.

## Audience

This guide is designed for use by analysts and developers who require guidance on data elements and components of the *HL7 Version 2.5.1 ORU Unsolicited Observation Message* relative to the Laboratory Results Interface (LRI) initiative. Users of this guide must be familiar with the details of HL7 message construction and processing starting with HL7 Version 2.5.1 through HL7 Version 2.8.2. This guide is not intended to be a tutorial on that subject.

### Relevant Laboratory Implementation Guides

There are multiple Implementation Guides that have been developed under the Office of the National Coordinator's (ONC) Standards and Interoperability Framework Initiative (S&I Framework). These guides have been created using the same processes, are stylistically similar and designed to work together. The set includes but is not limited to:

* This publication, the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 " US Realm* (LRI) in support of the lab result reporting to ambulatory care providers;
* *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 1 " US Realm,* (LOI) [[1] in support of the lab test ordering from ambulatory care providers and to provide data needed for reporting to Public Health;](#_ftn1)

* [*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2*](#_ftn1)

* *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)* (ELR) as a constrained profile of the LRI Implementation Guide;
* [*HL7 Version 2 Implementation Guide: Laboratory Value Set Companion Guide, Release 1- US Realm, September 2015*](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=413) providing cross-IG value set definitions and harmonized requirements.

The EHR System and LIS will conform to this family of Implementation Guides; a laboratory that receives an order conforming to the LOI IG should be capable of reporting results with a conformant LRI message.

[[1] Note that HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm is expected to be published in Q3 2015 and contains significant improvements; it is recommended implementers refer to that guide when available as it has been harmonized with this release of the LRI.](#_ftnref1)

### REQUISITE KNOWLEDGE

* HL7 V2.5.1 through V2.8.2 Messaging ([www.HL7.org](http://www.HL7.org))
* SNOMED CT (<http://www.ihtsdo.org/snomed-ct>)
* LOINC (<http://loinc.org>)
* UCUM (<http://unitsofmeasure.org>)
* OIDS (<http://www.hl7.org/oid>)
* [Standards and Interoperability Laboratory Results Interface Use Case, *Laboratory Results Reporting to Primary Care Providers (in an Ambulatory Setting) v1.0*](http://sibrowser.siframework.org/siclient/view?type=artifact&id=39481918-9dc7-4f55-aa77-f978b4c13d8b&name=SIFramework_LRI_UC.docx)

## Organization of this guide

### Conventions

This guide adheres to the following conventions:

* The guide is constructed assuming the implementer has access to the 2.5.1 through 2.8.2 versions of the HL7 Standard. Where there are variations from 2.5.1 the version that is used is referenced. Although some information from the standard is included in this Implementation Guide, much information from the standard has not been repeated here.
* The rules outlined in *HL7 2.7.1*, *Chapter 2B*, *Section 2B5*, *Conformance Using Message Profiles*, were used to document the use case for, and constraints applied to, the messages described in this guide.
* Data types have been described separately from the fields that use the data types.
* No conformance information is provided for optional message elements (O) or unsupported (X). This includes cardinality, value sets and descriptive information. Implementers who want to use optional message elements should refer to the base HL7 V2.5.1 Standard to determine how these optional message elements will be used. Conformance information is provided when a conditional predicate resolves to an R or RE on either the a or b part of the expression, regardless of the opposite value, e.g., C(R/O).
* This guide uses X as a conformance usage indicator very sparingly. Where the underlying standard indicates the segments/field/component is present for backwards compatibility (B) or withdrawn ("W") an X will be used. A small number of other message elements that are clearly out of scope for the use case have been given the "X" usage. All other message elements have either been further constrained to R/RE/C(a/b) or have been left as "O" to enable trading partners to explore additional capabilities. Labs would have insufficient information to populate these fields and if they would it would cause potential confusion with information present on the provider's system. Note that without a clearly agreed to complementary profile between trading partners, a Lab does not have to send any elements marked as an "O", nor does a receiver of a lab result have to process any elements marked as an "O". Neither trading partners can mandate the other to accept any such complementary profiles to enable basic laboratory results interfacing "out-of-the-box". The recipient should not return an error unless there is a clinical or regulatory impact as a result of discarding optional information.

### Message Element Attributes

The following table describes the various attributes used by this guide to document data type attribute tables, message structure attribute tables and segment attribute tables. Not all attributes apply to all attribute tables.

|  |  |
| --- | --- |
| Table1'1. Message Element Attributes | |
| Attribute | Definition |
| SEQ | Sequence of the elements as numbered in the HL7 message element. The SEQ attribute applies to the data type attribute table and the segment attribute table. |
| Component Name | Short name for the component. |
| Segment | Three-character code for the segment and the abstract syntax (e.g., the square and curly braces).  [ XXX ] Optional and singular  { XXX } Required and may repeat  XXX Required and singular  [{ XXX }] Optional and may repeat  Note that for segment groups there is no segment code present, but the square and curly braces will still be present.  The Segment attribute only applies to the Message attribute table. |
| DT | Data type used by this profile for HL7 element.  The data type attribute applies to data type attribute tables and segment attribute tables. |
| Usage | Usage of the message element for this profile. Indicates whether the message element (segment, segment group, field, component, or subcomponent) is R, RE, O, X or C(a/b) in the corresponding message element. Usage applies to the message attribute table, data type attribute table and the segment attribute table; see Section 1.3.4 Usage Conformance Rules. |
| Cardinality | Minimum and maximum number of times the element may appear.  [0..0] Element never present.  [0..1] Element may be omitted and can have, at most, one occurrence.  [1..1] Element must have exactly one occurrence.  [0..n] Element may be omitted or may repeat up to *n* times.  [1..n] Element must appear at least once, and may repeat up to *n* times.  [0..\*] Element may be omitted or repeat an unlimited number of times.  [1..\*] Element must appear at least once, and may repeat unlimited number of times.  [m..n] Element must appear at least *m*, and at most, *n* times.  Cardinality applies only to message attribute tables and segment attribute tables. |
| Value Set | The set of coded values to be used with the field. The value set attribute applies only to the data type attribute tables and the segment attribute tables. The value set may equate with an entire code system part of a code system, or codes drawn from multiple code systems. See Sections 1.4.7 Value Sets and 6 Code Systems. |
| Name | HL7 descriptor of the message element. Name applies to the message attribute table, data type attribute table and the segment attribute table. |
| Description/Comments | Context and usage for the element. Description/Comments applies to the message attribute table, data type attribute table and the segment attribute table. |

### Keywords

I would suggest this be controlled boilerplate, i.e., the output packaging pulls this from a library of boilerplate items (e.g., all the HL7 front matter), inserts it at the proper location in the file and sends it on. This is required to keep users from editing controlled definitions.

### USAGE CONFORMANCE RULES

The following text is pre-adopted from the HL7 V2.7.1 Conformance (Chapter 2B, 2.B.7.5). Please refer to the base standard documentation for a full explanation of conformance concepts. Usage is described here as it introduces the revised approach to conditional element handling; upon successful ballot and publication this material will be replaced with a reference to the normative documentation.

*---------- start citation---------*

2.B.7.5 Usage

Message content is governed by the cardinality specification associated (explicitly or implicitly) with each element of an HL7 message. Usage rules govern the expected behavior of the sending application and receiving application with respect to the element. The usage codes expand/clarify the optionality codes defined in the HL7 standard. Usage codes are employed in a message profile to constrain the use of elements defined in the standard. The usage code definitions are given from a sender and receiver perspective and specify implementation and operational requirements.

The standard allows broad flexibility for the message structures that HL7 applications must be able to receive without failing. But while the standard allows that messages may be missing data elements or may contain extra data elements, it should not be inferred from this requirement that such messages are conformant. In fact, the usage codes specified in a message profile place strict conformance requirements on the behavior of the application.

*Definition of Conditional Usage*

The conditional usage is defined as follows:

C(a/b) - a and b in the expression are placeholders for usage codes representing the true (a) predicate outcome and the false (b) predicate outcome of the condition. The condition is expressed by a conditional predicate associated with the element (See section 2.b.7.9, "Condition predicate"). a and b shall be one of R, RE, O and/or X. The values of a and b can be the same.

The example C(R/RE) is interpreted as follows. If the condition predicate associated with the element is true then the usage for the element is R-Required. If the condition predicate associated with the element is false then the usage for the element is RE-Required but may be empty.

There are cases where it is appropriate to value a and b the same. For example, the base standard defines the usage of an element as C and the condition predicate is dependent on the presence or non-presence of another element. The profile may constrain the element that the condition is dependent on to X; in such a case the condition should always evaluate to false. Therefore, the condition is profiled to C(X/X) since the desired effect is for the element to be not supported. Note it is not appropriate to profile the element to X since this breaks the rules of allowable usage profiling (see table HL7 Optionality and Conformance Usage).

Usage Rules for a Sending Application

|  |  |  |  |
| --- | --- | --- | --- |
| Optionality/Usage Indicator | Description | Implementation Requirement | Operational Requirement |
| R | Required | The application shall implement R elements. | The application shall populate R elements with a non-empty value. |
| RE | Required but may be empty | The application shall implement RE elements. | The application shall populate RE elements with a non-empty value if there is relevant data. The term relevant has a confounding interpretation in this definition [[1].](#_ftn1) |
| C(a/b) | Conditional | An element with a conditional usage code has an associated condition predicate (See section 2.B.7.9, Condition predicate that determines the operational requirements (usage code) of the element.  **If the condition predicate associated with the element is true, follow the rules for *a* which shall be one of R, RE, O or X:**  **If the condition predicate associated with the element is false, follow the rules for *b* which shall be one of R, RE, O or X**.  ***a*** and ***b*** can be valued the same. | |
| X | Not supported | The application (or as configured) shall not implement X elements. | The application shall not populate X elements. |
| O | Optional | None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X. | Not Applicable. |

Usage Rules for a Receiving Application

|  |  |  |  |
| --- | --- | --- | --- |
| Optionality/Usage Indicator | Description | Implementation Requirement | Operational Requirement |
| R | Required | The application shall implement R elements. | The receiving application shall process (save/print/archive/etc.) the information conveyed by a required element.  A receiving application shall raise an exception due to the absence of a required element. A receiving application shall not raise an error due to the presence of a required element, |
| RE | Required but may be empty | The application shall implement RE elements. | The receiving application shall process (save/print/archive/etc.) the information conveyed by a required but may be empty element. The receiving application shall process the message if the element is omitted (that is, an exception shall not be raised because the element is missing). |
| C(a/b) | Conditional | The usage code has an associated condition predicate true (See section 2.B.7.9, Condition predicate").  **If the condition predicate associated with the element is true, follow the rules for *a* which shall one of R, RE, O or X:**  **If the condition predicate associated with the element is false, follow the rules for *b* which shall one of R, RE, O or X**.  ***a*** and ***b*** can be the same. | |
| X | Not supported | The application (or configured) shall not implement X elements. | None, if the element is not sent.  If the element is sent the receiving application may process the message, shall ignore the element, and may raise an exception. The receiving application shall not process (save/print/archive/etc.) the information conveyed by a not-supported element. |
| O | Optional | None. The usage indicator for this element has not yet been defined. For an implementation profile all optional elements must be profiled to R, RE, C(a/b), or X. | None. |

*--------- end citation ---------*

[[1] There are multiple interpretations of RE when a value is known. One is the capability must always be supported and a value is sent if known, the other is the capability must always be supported and a value may or may not be sent even when known based on a condition external to the profile specification. The condition may be noted in the profile but cannot be processed automatically. This is what can be interpreted from the relevant part of the definition. Regardless of the interpretation the RE usage code, a set of test circumstances can be developed to sufficiently test the RE element. See the Conformity Assessment of Conformance Constructs section for more details.](#_ftnref1)

## Referenced profiles - antecedents

## Scope

### In Scope

### Out of Scope

## Key technical decisions [conventions]

# Use Cases

## Actors

## General Assumptions

### Assumptions

### Pre-conditions

### Post-conditions

## Use Case

### User Story

### Specific Assumptions

#### **Assumptions**

#### **Pre-conditions**

#### **Post-conditions**

### Scenario

### Context

[MISSING IMAGE: , ]Figure2'1. Context Diagram

### Interaction Model

### Functional Requirements

# Message Infrastructure

## Conformance Profiles

## Segments and Field Descriptions

## Datatypes

## Value Sets